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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------------|
| 10/538,655 | 12/23/2005 | Christian Pinset | CABH.P0002 | 3730 |
| 48947 | 7590 | 12/20/2007 | | |
| ADELI & TOLLEN, LLP 1875 CENTURY PARK EAST, SUITE 1360 LOS ANGELES, CA 90067 | | | EXAMINER HILL, KEVIN KAI | |
| | | | ART UNIT 1633 | PAPER NUMBER |
| | | | MAIL DATE 12/20/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,655

Applicant(s)

PINSET, CHRISTIAN

Examiner

Kevin K. Hill, Ph.D.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 31-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1 and 31-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Amendments

Applicant's response and amendments, filed October 18, 2007, to the prior Office Action is acknowledged. Applicant has cancelled Claims 2-30, amended Claim 1, and added new claims, Claims 31-54, thereby rendering the previous Requirement for Restriction moot.

Group I, claim(s) 1 and 31-54, drawn to a method for a functional treatment of small muscles selected from the group comprising urethral sphincters, anal sphincters, eyelid muscles, muscles of the fingers, and muscles of the larynx, in a mammal, the method comprising administering myoblasts obtainable by culturing said myoblasts in a cell culture medium.

1. **This application contains claims directed to the following patentably distinct species of cell culture media components within which myoblasts are to be cultured.**

The cell culture media component species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. Pinset et al (Differentiation 38(1):28-34, 1998; *of record in International Search Report) teach the culturing of myoblasts in a cell culture medium comprising fetal calf serum, insulin and at least one antioxidant and/or vitamin. Thus, the special technical feature of the invention, the myoblast obtained via the claimed cell culture conditions, does not contribute over the prior art. In addition, these cell culture media component combination species are not obvious variants of each other based on the current record.

The claims (claims 1, 32, 34-35, 38-45, 48, and 54) recite a plurality of alternative cell culture media components, and combinations thereof. Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed cell culture media component species, or specific combination thereof, for prosecution on the merits to which the claims shall be restricted.

This application contains claims directed to the following patentably distinct species of alternative method step species recited in claims 46-47 and 51-52. The alternative method step species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. In addition, these alternative method step species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed alternative method step species, or specific combination thereof, for prosecution on the merits to which the claims shall be restricted.

This application contains claims directed to the following patentably distinct species of small muscle tissue species to be treated by the inventive cultured myoblasts, as recited in claims 1, 48 and 54. The alternative tissue species are independent or distinct because the species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. One of ordinary skill in the art recognizes that eyelids are distinctly different anatomical and physiological tissues than anal sphincters, and that finger muscles are distinctly different anatomical and physiological tissues than the larynx. In addition, these small muscle tissue species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed small muscle tissue species for prosecution on the merits to which the claims shall be restricted.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

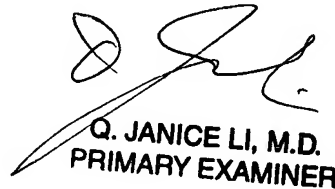
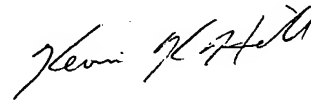
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Q. JANICE LI, M.D.
PRIMARY EXAMINER